UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION

Case No. 21-cv-03825-AMO

ORDER RE: CROSS MOTIONS FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 149, 153

FILED UNDER SEAL

This is an antitrust case related to surgical robots, their instruments, and whether the robot's manufacturer has engaged in anticompetitive conduct. This is one of two related cases before the Court alleging anticompetitive conduct by Defendant Intuitive Surgical, Inc. ("Intuitive").[1] The two cases involve similar antitrust claims – this case is brought by customers, and the other case is brought by a competitor. The parties' cross-motions for summary judgment were heard before this Court on September 7, 2023. Having read the papers filed by the parties and carefully considered their arguments therein and those made at the hearing, as well as the relevant legal authority, the Court **GRANTS in part and DENIES in part** Plaintiffs' Motion for Summary Adjudication, and the Court **DENIES** Defendant's Cross-Motion, for the following reasons.

[1] The related case is *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, N.D. Cal. Case No. 3:21-cv-03496-AMO. The Court simultaneously enters its order on the pending cross-motions for summary judgment in that case.

BACKGROUND[2]

I. FACTUAL BACKGROUND

Defendant Intuitive Surgical, Inc. ("Intuitive") manufactures sophisticated medical devices used to perform surgery. Named Plaintiffs Larkin Community Hospital, Franciscan Alliance, Inc., and King County Public Hospital District No. 1 (dba Valley Medical Center) (together "Hospital Plaintiffs") all own devices produced by Intuitive.

A. Intuitive and the Da Vinci

Intuitive designs, manufactures, and sells minimally invasive surgical robots ("MISR") known as da Vinci Surgical Systems ("da Vinci"). In 2000, Intuitive's da Vinci became the first surgical robot approved by the United States Food and Drug Administration ("FDA"). Corrigan Decl. Ex. 1 (Elhauge Report) ¶¶ 23-24. In 2003, Intuitive acquired Computer Motion and phased out Computer Motion's Zeus surgical robot, leaving the da Vinci as the only surgical robot capable of performing soft tissue surgery (between a patient's pelvis and neck) with a meaningful market share in the U.S. – a distinction it has held ever since. *Id.* ¶ 21. Plaintiffs present evidence from an expert that Intuitive has maintained a share of the surgical robot market that exceeds 99% for the past several years. *Id.* ¶ 112.

Intuitive additionally manufactures the surgical instruments that work with the da Vinci system, called EndoWrists. EndoWrists are surgical instruments attached to the da Vinci's mechanical arms, which are suspended above the patient. Rosa Decl. ¶ 9. EndoWrists include fine wire cables that thread through a complex pulley system, allowing the surgeon to move the surgical instruments easily inside the patient's body to desired angles with great precision, mimicking and even exceeding the range of motion of the human wrist. Rosa Decl. ¶ 24. EndoWrists allow for more dexterous surgical motions and additional degrees of freedom relative to traditional laparoscopic surgical instruments. Elhauge Report ¶ 38.

[2] The Court must view the facts in the light most favorable to the non-moving party and give it the benefit of all reasonable inferences to be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Olsen v. Idaho State Bd. of Med.*, 363 F.3d 916, 922 (9th Cir. 2004).

Intuitive controls the frequency of EndoWrist instrument replacement by way of a built-in self-destruct mechanism it calls a "use counter." Rosa Decl. ¶¶ 36-37. The use counter is a memory chip within each EndoWrist instrument that decrements every time the instrument is used in surgery, without regard to the actual time or rigor of usage of the EndoWrist in the surgery. Corrigan Decl. Ex. 7 (Rubach Report) ¶¶ 30-32; Rosa Decl. ¶¶ 36-37. When the use count (until recently, 10 uses in most instruments) reaches zero, the da Vinci system will no longer recognize the EndoWrist instrument, which is rendered useless. *See* Rosa Decl. ¶ 36; Rubach Report ¶¶ 18, 30; Elhauge Report ¶ 42. Intuitive developed the use counter through testing, and the company views the restrictions imposed by the use counter as an essential feature for instrument safety and effectiveness that was reviewed by FDA in its approval of the da Vinci system. Rosa Decl. ¶¶ 23, 28-29. Intuitive considers the use counter essential because instrument failure can occur in multiple ways, including (among others) metal fatigue of the fine wire cables, breaks in the intricate pulley system, and failure of the apparatus to maintain the needed precision of movement. Rosa Decl. ¶ 27; *see* Cahoy Decl. Ex. 3 (Howe Report) ¶¶ 36, 75. Although the use limits were described in Intuitive's submissions to the FDA to obtain agency approval of the EndoWrist, the parties offer conflicting evidence as to whether the limits serve any legitimate medical or patient safety purpose. *Compare* Rosa Decl. ¶¶ 22-35, 45, *with* Rubach Report ¶¶ 28-36.

Da Vinci systems have evolved over time, and Intuitive has introduced new models from time to time, with support eventually being phased out for outdated models. Rosa Decl. ¶ 11. The "Si" systems were introduced in 2009. *Id.* Intuitive ceased selling new Si systems in the United States in 2018 and is expecting to cease support for those systems, including the sale of new S/Si EndoWrists, in 2024, ten years after introducing the successor Xi model. *Id.*; Cahoy Decl. Ex. 2 (Shaw Dep.) at 172:13-174:12. The models that are primarily used today in the United States are the Xi, introduced in 2014, and the X, introduced in 2017. Rosa Decl. ¶ 11.

Each purchaser or lessor of a da Vinci enters into a contract with Intuitive, typically a Sales, Licensing and Service Agreement ("SLSA") or corresponding lease agreement. *See* Rosa Decl. ¶ 21; *see, e.g.*, Cahoy Decl. Ex. 12 (Conway Regional Medical Center, Inc., SLSA). Intuitive's contracts with its customers (hospitals and other surgery centers) have prohibited

(a) any repair or modification of EndoWrists, and (b) the use of EndoWrists beyond the maximum number of uses mandated by Intuitive. *See id.*; Intuitive's Answer (ECF 74) ¶¶ 4, 107. The contracts typically prohibit customers from modifying, altering, or misusing the system and its components or manipulating the software. *See, e.g.*, SLSA §§ 3.2, 4, 5.2. Intuitive also disclaims warranty obligations for claims arising from repairs, modifications, or other changes made by a third party. *See, e.g.*, SLSA §§ 5.2(E), 10.1. If a da Vinci customer violates these provisions, the contract provides that Intuitive may cease servicing the robot, cancel its warranty, terminate the contract, and withhold the sale of instruments and replacement parts. Intuitive's Answer (ECF 74) ¶¶ 73, 107; SLSA §§ 5.2(E), 10.1. "Such provisions concerning the use of the system and instruments have been included in the agreements since 1999." Cahoy Decl. Ex. 17 (Smith Report) ¶ 84(a).

B. EndoWrist Repair

Sometime around 2014, a company called Rebotix Repair, LLC ("Rebotix") developed a computer chip called the "Interceptor" that could be inserted inside an Si EndoWrist to "intercept" the data in the instrument chip's memory and circumvent the use counter to extend the useful life of an EndoWrist instrument. *See* Cahoy Decl. Ex. 14 (software description of Rebotix Interceptor) at -1000; Corrigan Decl. Ex. 18 (historical timeline of repair service development and marketing). In 2016, Rebotix began marketing and performing its repair services internationally. Corrigan Decl. Ex. 18. In 2018, Rebotix entered the U.S. market and licensed its repair technology to Restore Robotics LLC ("Restore") to operate a U.S. EndoWrist service center. *Id.* Established medical supply companies including Surgical Instrument Service Co. ("SIS") and Medline also reached deals with Rebotix and Restore to provide EndoWrist repairs on a large scale, with SIS, for example, entering into an agreement with Vizient, one of the nation's largest healthcare group purchasing organizations, to provide such services to Vizient members. Corrigan Decl. Ex. 23 (Posdal Dep.) 13:19-14:16, 15:14-18:7, Ex. 2; Corrigan Decl. Ex. 24 (Colletti Dep.) 7:24-10:5.[3]

[3] The Court hereafter refers to third-party repair entities such as Rebotix, Restore, and SIS as independent repair companies ("IRC" or "IRCs").

Medical facilities expressed interest and became repeat customers of the repair service. Corrigan Decl. Ex. 27 (Papit Dep.) 86:21-87:9; Ex. 28 (internal Intuitive Report titled "Unauthorized Instrument Reprogramming Overview," Intuitive-00194074), at -075, -077. Restore and Rebotix offered cost savings of 40-50% off Intuitive's list price for the repaired instruments, which hospitals and surgeons viewed as functionally equivalent to new EndoWrists. Papit Dep. 180:24-181:4; Corrigan Decl. Ex. 6 (Harrich Dep.) 38:9-13. Beginning in 2018, Intuitive responded by sending cease-and-desist letters to both Rebotix and Restore, *see, e.g.*, Corrigan Decl. Ex. 29 (letter to Restore (Intuitive -00478439)), and to medical facilities that used or even considered using repaired instruments, *see* Ex. 16 (Jones Dep.) 36:10-37:7, 80:1-82:16. Intuitive's cease-and-desist letters to its customers warned that using repaired instruments is a "material breach" of their agreement that could result in the termination of service support for the robot, any warranties, and the agreement itself. Corrigan Decl. Ex. 30 (letter to Evergreen Healthcare (Intuitive-00372993)) at -994-95.

In 2016, Intuitive began evaluating an instrument refurbishing program of its own, known as "Project Dragon." Corrigan Decl. Ex. 41 (Intuitive-00273261); Ex. 35 (Intuitive-00102938). Project Dragon aimed to "displace" and increase barriers to entry for third-party repair companies. Corrigan Decl. Ex. 11 (DeSantis Dep.) 254:19-24; Ex. 34 (Scoville Dep.) 85:10-23. Intuitive additionally sought to extend the use limits of certain da Vinci X and Xi instruments. Corrigan Decl. Ex. 42 (Intuitive-00029174), at -174; Ex. 43 (Intuitive-00583036), at -036-43; Ex. 59 (Intuitive- 00471993) at -994 (all internal Intuitive correspondence and reports regarding use limit extension).

C. FDA & Section 510(k) Clearance

The da Vinci robot and EndoWrist instruments fit within a regulatory scheme that shapes the parties' arguments in the pending motions. The Food, Drug and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"), 90 Stat. 539, (codified at 21 U.S.C. § 301 et seq.) requires that medical devices like the da Vinci and its components receive certain approvals from FDA. "The MDA separates devices into three categories: Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general

manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices present a potential unreasonable risk of illness or injury and therefore incur the FDA's strictest regulation." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (internal quotation marks and alteration omitted). Manufacturers or remanufacturers of Class II devices need only submit a "premarket notification" to the FDA in accordance with the less burdensome "510(k) process" rather than the more rigorous process of obtaining "premarket approval" from the FDA necessary for manufacturers of Class III devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-79 (1996) (contrasting the two procedures); *see also* 21 C.F.R. § 807.81(a). "Section 510(k)" refers to the section of the original MDA containing this provision, and it sets forth the procedure by which a medical device that is "substantially equivalent" to a device that is already on the market can be cleared for sale without undergoing the more rigorous pre-market review and approval process. *See* 21 U.S.C. § 360(k); *see also Medtronic*, 518 U.S. at 478-79.[4]

The parties disagree as to whether third parties' services require Section 510(k) clearance from the FDA, and the FDA's position on the matter is less than clear. Rebotix first sought regulatory clearance of its procedure in December 2014. Cahoy Decl. Ex. 1 (Foreman Report) ¶ 103, Ex. 21 (Rebotix 510(k) application). FDA responded by identifying deficiencies in the application and warning Rebotix that it could not place remanufactured instruments into commercial distribution unless and until it received FDA clearance. Cahoy Decl. Ex. 23 (FDA email to Rebotix dated June 23, 2015). In response, Rebotix withdrew its application in December 2015. Cahoy Decl. Ex. 24 (Rebotix letter to FDA dated December 17, 2015).

Rebotix initiated a new business model in 2018 in which hospitals retained ownership of their used Si EndoWrists and hired Rebotix to modify the instruments. Cahoy Decl. Ex. 20 (Papit

[4] "Remanufacturer" is defined in in the Federal Regulations as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." 21 C.F.R. § 820.3(w). Because there is a dispute about whether SIS's treatment of the EndoWrists constitutes "repair" or "remanufacturing" and the term of art used appears to determine the legal outcome of the case, the Court generally refers to the treatment as "service" to the extent possible in this order.

Dep. from *Rebotix* case) at 210:9-21, 227:10-23. Rebotix entered into a relationship with Restore Robotics ("Restore"), which was to market the Rebotix process to hospitals, buy the Interceptor chips from Rebotix, and modify the instruments. *Id.* Ex. 28 (Rebotix & Restore "Distributor Agreement"). Rebotix terminated the contract in late 2019. *Id.* Ex. 20 (Papit Dep. from *Rebotix* case) at 132:12-21. Rebotix also entered into an arrangement with SIS under which SIS would market the Rebotix service to hospitals and Rebotix would perform the modifications. *Id.* Ex. 29 (Johnson Dep.) at 19:2-8, 33:22-34:4.

Following an inquiry from a Rebotix distributor, FDA stated that Section 510(k) clearance was required for resetting the use counter because "if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed," which would constitute "remanufactur[ing]." Cahoy Decl. Ex. 31 (FDA email correspondence) at -0335. That correspondence expressly stated that the message constituted "an informal communication" that did "not necessarily represent the formal position of FDA, and [did] not bind or otherwise obligate or commit the agency to the view expressed." *Id.* at -0335-36. In February 2020, an FDA representative emailed Rebotix directly, stating that "a 510(k) is needed before [Rebotix] continue[s] [its] operation." Cahoy Decl. Ex. 34 (FDA email correspondence) at -6955. Following further communications with the agency, Restore informed the agency that it had elected to exit the business. Cahoy Decl. Ex. 38 at -1249.

Restore then worked with a third party, Iconocare, to submit an application for FDA clearance. Cahoy Decl. Ex. 39 (Parker Dep.) at 204:16-205:17, 213:19-216:23. FDA conducted an extensive review process that required additional testing and procedural adjustments by Iconocare, and on September 30, 2022, Iconocare received clearance on its limited application. Cahoy Decl. Ex. 1 (Foreman Report) ¶ 136; Corrigan Decl. Ex. 83 (FDA correspondence). In the course of granting this clearance, FDA described the modification to reset the use counter as "remanufacturing," which required Section 510(k) clearance. Foreman Report ¶¶ 129, 136; Cahoy Decl. Ex. 41 (FDA deficiency notice to Iconocare) at -0535.

Separately, in Rebotix's communications with FDA regarding its activities, the company received email correspondence from a Team Lead at the FDA stating as follows:

> As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted.
>
> The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. This includes, but is not limited to, items such as electrical safety, reprocessing, software, and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition.

Cahoy Decl. Ex. 37 (email dated April 8, 2022).[5] In response to this correspondence from FDA, Rebotix suggested that it would appeal FDA's regulatory determination that the EndoWrist services constituted remanufacturing, to which the same Team Lead clarified that his message was not an "official regulatory evaluation." *Id.* (email dated July 22, 2022). Rather, the correspondence quoted above represented informal comments following a "preliminary informal assessment" of limited materials and did "not represent the formal position of FDA" or any position that was appealable. *Id.*

D. Plaintiffs

Hospital Plaintiffs are three entities that own da Vinci systems. They seek to represent a putative class of other da Vinci purchasers.[6]

Plaintiff Larkin Community Hospital ("Larkin") operates two hospitals in Florida. Cahoy Decl. Ex. 46 (Sosa-Guerrero Dep.) at 11:8-12:6. In 2017, it leased two da Vincis, an Si and an Xi.

[5] The parties submitted this correspondence under seal. However, the Court provides this portion of the correspondence in its public order because it has already been made public in another case, *Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, No. 8:20-CV-2274-VMC-TGW, 2022 WL 3272538 (M.D. Fla. Aug. 10, 2022), discussed further below.

[6] The case schedule in this matter and the related matter (*Surgical Instrument Service Co. v. Intuitive Surgical, Inc.*, N.D. Cal. Case No. 3:21-cv-03496-AMO), necessitated considering dispositive motions prior to class certification. The Court will discuss a proposed schedule for class certification at a future date.

Id. Ex. 11. Larkin returned its Si system to Intuitive in 2022 and currently has only an Xi system. Bair Decl. ¶ 9.

Plaintiff Franciscan Alliance ("Franciscan") operates several hospitals in the Midwest. Cahoy Decl. Ex. 48 (Franciscan resps. to interrogs.) at 13-14. It previously owned several da Vinci Si systems, but it replaced them over time between 2015 and 2020 and currently operates only da Vinci Xi systems. *Id.*

Plaintiff King County Public Hospital District No. 1, dba Valley Medical Center ("Valley") traded in its only Si system in 2019 and currently owns two Xi systems. Cahoy Decl. Ex. 50 (Wagner Dep.) at 43:12-44:1, 135:23-136:5.

Franciscan and Valley had long-term service contracts with Intuitive throughout the relevant period; Larkin had a service contract for part of the period. Bair Decl. ¶ 9.

II. PROCEDURAL POSTURE

Hospital Plaintiffs' operative complaint asserts six antitrust causes of action against Intuitive. ECF 52. The Hospital Plaintiffs claim that Intuitive created schemes of tying, exclusive dealing, and monopolization in the market for servicing the da Vinci robots in violation of Sections 1 and 2 of the Sherman Act, Title 15 U.S.C. §§ 1, 2. ECF 52. Further, Hospital Plaintiffs allege that Intuitive created schemes of tying, exclusive dealing, and monopolization in the EndoWrist repair and replacement aftermarket in violation of Section 1 and 2 of the Sherman Act. *Id.*

Hospital Plaintiffs move for summary adjudication on two sets of issues that stop short of seeking judgment on all claims. They first ask for judgment that (a) surgical robots and EndoWrists occupy different markets, and (b) Intuitive enjoys monopoly power in both markets. Plaintiffs also seek judgment on the issue of antitrust injury. *Id.*

In opposition, Defendant counters that Plaintiffs cannot establish that Intuitive's conduct proximately caused their antitrust injury. Defendant argues that its actions cannot be considered the source of Plaintiffs' injury because (1) FDA regulations prohibited remanufacturing EndoWrists without Section 510(k) clearance; (2) these Plaintiffs had no interest in using remanufactured EndoWrists; and (3) to the extent Plaintiffs' claims relate to X/Xi EndoWrists, no

potential competitor has ever had the ability to re-set those devices. In addition to opposing Hospital Plaintiffs' motion, Intuitive seeks summary judgment on all of Plaintiffs' antitrust claims. ECF 153.

LEGAL STANDARD

A party may move for summary judgment on a "claim or defense" or "part of . . . a claim or defense." Fed. R. Civ. P. 56(a). Summary judgment is appropriate when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. *Id.* The party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Material facts are those that might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. *Id.*

Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir. 2007). On an issue where the nonmoving party will bear the burden of proof at trial, the moving party may carry its initial burden of production by submitting admissible "evidence negating an essential element of the nonmoving party's case," or by showing, "after suitable discovery," that the "nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial." *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1105-06 (9th Cir. 2000); *see also Celotex*, 477 U.S. at 324-25 (moving party can prevail merely by pointing out to the district court that there is an absence of evidence to support the nonmoving party's case).

When the moving party has carried its burden, the nonmoving party must respond with specific facts, supported by admissible evidence, showing a genuine issue for trial. Fed. R. Civ. P. 56(c), (e). But allegedly disputed facts must be material – the existence of only "some alleged

factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." *Anderson*, 477 U.S. at 247-48.

When deciding a summary judgment motion, a court must view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in its favor. *Id.* at 255; *Hunt v. City of Los Angeles*, 638 F.3d 703, 709 (9th Cir. 2011). However, when a non-moving party fails to produce evidence rebutting defendants' showing, then an order for summary adjudication is proper. *Nissan Fire*, 210 F.3d at 1103 ("If the nonmoving party fails to produce enough evidence to create a genuine issue of material fact, the moving party wins the motion for summary judgment."). The court's function on a summary judgment motion is not to make credibility determinations or weigh conflicting evidence with respect to a disputed material fact. *See T.W. Elec. Serv., Inc., v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

DISCUSSION

The Hospital Plaintiffs move for summary adjudication on certain market definitions and on whether Section 510(k) clearance precludes them from establishing antitrust injury. Because a "threshold step in any antitrust case is to accurately define the relevant market," the Court first considers these aspects from the Hospital Plaintiffs' Motion. *Fed. Trade Comm'n v. Qualcomm Inc.*, 969 F.3d 974, 992 (9th Cir. 2020) (stating that courts must first accurately define the market before assessing restraints on competition and resulting antitrust injuries). The Court then considers the issues related to antitrust injury, including the necessity of Section 510(k) clearance, in the discussion of Intuitive's Cross-Motion, below. *See id.*

I. PLAINTIFFS' MOTION

The Hospital Plaintiffs seek summary adjudication of several issues related to the relevant markets. The Court takes up these issues in turn.

A. Separate Products

The Hospital Plaintiffs advance that there are two distinct products at issue: the da Vinci as a minimally invasive soft tissue surgical robot, and the EndoWrist instruments that are attached to and used with the robot. In the case related to this one, Judge Chhabria considered this issue in its order resolving Intuitive's motion to dismiss. *Surgical Instrument Serv. Co. v. Intuitive Surgical,*

Inc. ("*SIS*"), 571 F. Supp. 3d 1133 (N.D. Cal. 2021). There, the court described that "whether one or two products are involved turns not on the functional relation between them, but rather on the character of the demand for the two items." *Id.* at 1139 (quoting *Jefferson Parish Hosp. v. Hyde*, 466 U.S. 2, 19 (1984)). "[S]eparate markets exist in situations where consumers, 'when given a choice,' opt to purchase the goods from different firms, rather than a single firm." *Id.* at 1139 (quoting *Rick-Mik Enterprises, Inc. v. Equilon Enterprises LLC*, 532 F.3d 963, 975 (9th Cir. 2008)). The court stated further, "The Supreme Court has long recognized that complementary products – however essentially paired – can constitute separate product markets." *Id.* (citing *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 462-63 (1992)). Especially relevant here, "[i]f complementary products could never occupy distinct product markets, 'there [could] never be separate markets, for example, for cameras and film, computers and software, or automobiles and tires.'" *Id.* (quoting *Kodak*, 504 U.S. at 463).

Here, there exists no dispute that EndoWrists are bought separately from and not in a fixed ratio with the da Vinci robot. *See* SLSA § 8 ("Instruments . . . will be made available . . . pursuant to separate orders placed . . . from time to time in accordance with the terms and conditions of the then current Instrument and Accessory Catalog."). Further, the Hospital Plaintiffs present several forms of evidence to show that, when given a choice (and even despite threats and limitations from Intuitive), several health care providers opted to purchase aftermarket EndoWrist services from IRCs. *See* Corrigan Decl. Ex. 28 (Intuitive presentation counting 18 U.S. accounts that had used reprogramed EndoWrists as of 2019); Ex. 49 (list of Rebotix's invoices including EndoWrist repair); Ex. 50 (sales report from Restore including EndoWrist repair); Ex. 51 (list of SIS transactions including EndoWrist repair). The evidence shows that several hospitals viewed repaired EndoWrists as functionally equivalent to new EndoWrists from Intuitive. Corrigan Decl. Ex. 6 (Harrich Dep.) 36:17-39:9; 62:6-10, 69:8-16; Ex. 36 (Madewell Dep.) 47:9-25, 117:5-118:1; Ex. 39 (McDonald Dep.) 1720-19:20; Ex. 40 (Harvey Dep. 21:2-14, 58:20-24; Ex. 38 (Bair Dep.) 151:13-158:9. The evidence further shows that many hospitals – including Plaintiff Franciscan and Hospital Corporation of America ("HCA"), one of the largest hospital chains in the nation – demonstrated interest in unbundled EndoWrist repair services but were deterred by Intuitive's

conduct. Corrigan Decl. Ex. 1 (Elhauge Report) ¶¶ 273, 304; Ex. 19 (Intuitive letter to HCA responding to HCA's interest in IRC-repaired EndoWrists), at -082; Ex. 52 (Schimmel Dep.) 93:16-95:13; Ex. 23 (Posdal Dep.) 77:14-78:20. These facts demonstrate that there was demand for EndoWrist repair and replacement separate from demand for da Vinci robots.

Even Intuitive treats EndoWrists as products separate from da Vinci robots. In its Securities and Exchange Commission ("SEC") filings, Intuitive publicly acknowledged its product offerings separately: "systems" include the da Vinci robot while "instruments and accessories" include EndoWrists. Corrigan Decl. Ex. 54 (Intuitive 10-5 (FY 2020)) at 6-8. The da Vinci robot is a single capital purchase, while EndoWrists are continually purchased over time. Corrigan Decl. Ex. 15 (Vavoso Dep.) 50:20-51:9.

Intuitive insists that genuine issues of material fact preclude summary adjudication on the issue of whether the da Vinci and EndoWrists are separate products. In support, Intuitive cites to the declaration of its economic expert, Dr. Loren K. Smith, which advances that the da Vinci constitutes a single system rather than distinct robots and instruments. Smith Decl. Ex. 1 (Smith Report) ¶¶ 68-102. Intuitive additionally cites to customer contracts and materials given to customers in advance of purchase explaining the customer's investment in the da Vinci system. *See, e.g.*, Cahoy Decl. Ex. 11 (Larkin-Intuitive Use, License & Service Agreement) § 8; Rosa Decl. ¶¶ 14-21 & Ex. 1 at -1263, -1274, -1305-09. Intuitive's evidence, however, falls short of creating a genuine dispute of material fact because the expert's explanation that the components constitute a single functional system does not conflict with the distinct demand for da Vinci robots and the EndoWrist instruments. *See Jefferson Parish Hosp.*, 466 U.S. at 19; *see also United States v. Microsoft Corp.*, 253 F.3d 34, 86 (D.C. Cir. 2001) ("The mere fact that two items are complements, that one . . . is useless without the other does not make them a single product for purposes of tying law."). The relevant portion of Dr. Smith's report focuses almost exclusively on Intuitive's design and marketing of the da Vinci robot and EndoWrists as a collective system. Smith Report ¶¶ 68-102. In so doing, the expert's report fails to confront, much less contradict, evidence that there is an independent demand for replacement EndoWrists after the initial purchase of the system. Additionally, the expert's report and the materials provided upon initial

purchase of a da Vinci system further fail to contradict evidence that health care providers expressed interest in and purchased aftermarket EndoWrist services on several occasions as described above. *See, e.g.*, Corrigan Decl. Ex. 28. Thus, Intuitive fails to establish a genuine dispute regarding separate customer demand for the da Vinci and for the EndoWrist. Despite Intuitive's contentions that the da Vinci and EndoWrists are essentially paired, Intuitive fails to rebut that the robots and the instruments occupy separate product markets. *See Eastman Kodak Co.*, 504 U.S. at 462-63. To the contrary, the uncontroverted evidence shows that "when given a choice," health care providers opted to purchase aftermarket EndoWrist services separately from the da Vinci, including from IRCs. *Rick-Mik*, 532 F.3d at 975. Therefore, there is no genuine issue of material fact that the da Vinci surgical robot and EndoWrists are separate products, and the Hospital Plaintiffs are entitled to summary adjudication on this issue.

B. Da Vinci Surgical Robot – Market Definition

Plaintiffs additionally move to establish that Intuitive enjoys monopoly power in the markets for both da Vinci robots and EndoWrist instruments. The Court first considers the proposed market definition related to surgical robots.

To "plead a relevant market" for purposes of a Sherman Act claim, a plaintiff must allege "both a geographic market and a product market." *Hicks v. PGA Tour, Inc.*, 897 F.3d 1109, 1120 (9th Cir. 2018). Neither party disputes that the relevant geographic market in this case is the United States. A product market consists of the product at issue and all economic substitutes for that product. *Newcal Indus., Inc. v. Ikon Off. Sol.*, 513 F.3d 1038, 1045 (9th Cir. 2008). "Economic substitutes," the Ninth Circuit states,

> have a "reasonable interchangeability of use" or sufficient "cross-elasticity of demand" with the relevant product. Including economic substitutes ensures that the relevant product market encompasses "the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels of business."

Hicks, 897 F.3d at 1120 (internal citation omitted). Determining the relevant market is typically a fact-intensive inquiry, involving "identification of the field of competition: the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels

of business." *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1374 (9th Cir. 1989). For that reason, determining the relevant market is generally left to a jury. *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1203 (9th Cir. 1997).

The Hospital Plaintiffs present significant record and expert evidence to establish that surgical robots constitute a distinct product market because laparoscopic and open surgery, functional alternatives, are not economic substitutes for surgical robots. For example, Plaintiffs advance that surgical robots provide greater physical functionality, allowing surgeons to perform surgeries that are difficult or impossible to perform through laparoscopic or open modalities. *See* Corrigan Decl. Ex. 1 (Elhauge Report) ¶ 93; Ex. 57 (Dickens Dep.) 13:9-20; Ex. 61 (Zafar Dep.) 217:25-218:8. Plaintiffs advance that both surgeons and patients – two important constituencies for health care providers – demand surgical robots. *See id.* Ex. 62 (Pope Dep.) 27:19-25; Ex. 63 (Donovan Dep) 15:7-16; Ex. 6 (Harrich Dep) 12:16-18, 125:13-17; Ex. 4 (Francis Dep.) 36:6-11; Ex. 64 (Bernier Dep.) 28:3-12; Ex. 58 (Estape Dep.) 65:1-12. Further, Plaintiffs present evidence that Intuitive acknowledges and even boasts that its surgical robots are in a market of their own. *See id.* Ex. 2 (Curet Dep.) 8:16-22 (Intuitive's Chief Medical Officer testified that MIRS is a "revolution" over laparoscopic surgery); *see also* Ex. 66 (Intuitive report, "Managing the Long Tail of da Vinci Si" (Intuitive-02068246)) at -246-297; Ex. 67 (notes made in preparation for industry panel discussion (Intuitive-00269124)) at -126 ("We do not see ourselves in competition with laparoscopy."); Ex. 68 (Intuitive PowerPoint presentation describing competitive landscape (Intuitive-00560277)) at -381-384; Ex. 70 at 7 (Intuitive's CFO observing that "competition isn't yet here" during a global healthcare conference presentation).

Despite Plaintiffs' robust showing, however, Intuitive raises a genuine dispute of fact regarding market definition. Intuitive's economic expert concludes that the relevant market must include at least laparoscopy surgery, particularly where laparoscopy remains the majority surgery of choice for many types of surgery. Smith Decl. Ex. 1 ¶¶ 103-36, Table 1. The conflict between Dr. Smith's report and Dr. Elhauge's report creates a genuine issue of material fact as to the appropriate market definition. *See DeLew v. Adamson*, 293 Fed. App'x. 504, 506 (9th Cir. Sept. 17, 2008) ("The existence of conflicting expert assessments suggests that neither party is entitled

to summary judgment."); *see also Garter-Bare Co. v. Munsingwear, Inc.*, 650 F.2d 975, 982 (9th Cir. 1980). Because there exists a genuine dispute as to whether surgical robots constitute a distinct market that can be separated from laparoscopy and open surgery, the Court DENIES Plaintiffs' motion on this basis.

C. EndoWrist Instruments – Market Definition and Monopoly Power

The Hospital Plaintiffs additionally move for summary adjudication regarding (1) the definition of the market for EndoWrist repair and replacement and (2) Intuitive's power in that market. The Court addresses these issues in turn.

1. U.S. Market for EndoWrist Repair and Replacement

Intuitive argues that there cannot exist a distinct market for "EndoWrist repair and replacement" because there is no evidence of any market demand for genuine "repair" of EndoWrists. Intuitive advances this argument on two bases.

The first basis for Intuitive's argument that there is no market for EndoWrist repair relates to whether any of the IRCs provided genuine "repair" services as that term is defined under FDA regulations. But, for the reasons discussed below, the Court does not conclude whether the services constituted "repair" or "remanufacture," only that FDA brought no enforcement action to establish that the services violated its regulations. Intuitive's argument that none of the IRC services constituted repair therefore cannot invalidate Plaintiffs' proposed EndoWrist market definition.

The second basis for Intuitive's argument that there is no market for EndoWrist repair arises from the deposition testimony of hospital witnesses that, if 510(k) clearance were required for EndoWrist repair, and if a repair service provider lacked FDA clearance, then those hospitals would not use the uncleared instruments. Cahoy Decl. Ex. 67 (Schimmel Dep.) at 51:24-52:8, Ex. 68 (Teal Dep.) at 37:11-25, 43:2-8, Ex. 69 (Early Dep.) at 58:13-18. Intuitive argues, based on this testimony, that no market can exist for repaired EndoWrists because there was no customer demand for such repaired instruments. But the evidence Intuitive proffers fails to create a material factual issue because, as the Hospital Plaintiffs elucidate, the testimony discusses a hypothetical circumstance that did not exist. Intuitive asked each of the witnesses – directors of supply chain,

chief financial officers, etc. – whether their respective hospitals would require evidence of 510(k) clearance before contracting with IRCs *if* FDA required 510(k) clearance for EndoWrist repair, and each of them answered in the affirmative. *See, e.g.*, Spector Decl. Ex. 132 (Teal Dep.) at 37:18-19 ("[I]f the FDA requires a device to be cleared, . . . we would purchase a cleared device."). In relying on this testimony, Intuitive assumes that FDA requires 510(k) clearance for the services provided by the IRCs, a legal conclusion contradicted by the evidence in the record. The evidence in the record demonstrates that the FDA has not taken any action to require 510(k) clearance. *See* Cahoy Decl. Ex. 37 (email from FDA dated July 22, 2023, stating that earlier correspondence was not an "official regulatory evaluation"). Thus, the testimony of the Hospital Plaintiffs' witnesses concerns a hypothetical circumstance in which Section 510(k) clearance is required for EndoWrist repair services, which fails to create a genuine dispute of fact as to healthcare providers' interest in repaired EndoWrists. Indeed, the Hospital Plaintiffs expressed interest in the IRC services; for example, Larkin considered using IRC Revanix to reset/repair its EndoWrists to save money on its robotic surgeries. Spector Decl. Ex. 134 (Gonzalez Dep.) at 14:10-15:4 (describing "conversations" with Revanix about "reset[ting] the counter on the instruments" and "lowering the cost of the surgery by extending the life of the instrument").

In advancing the arguments regarding the lack of any genuine repair services and the lack of any market demand for repaired EndoWrists, Intuitive fails to present any evidence contradicting the evidence presented by Hospital Plaintiffs demonstrating the existence of a distinct market for EndoWrist instruments. Hospital Plaintiffs demonstrate that the field of competition for EndoWrist instruments is limited because EndoWrists are necessary to perform surgeries with the da Vinci – no other instruments work with the robot. *See* Corrigan Decl. Ex. 15 (Vavoso Dep.) 53:17-55:16. Repaired EndoWrists are practical substitutes for EndoWrists and accordingly fall in the same product market as new EndoWrists. *Id.* Ex. 1 (Elhauge Report) ¶ 158; Ex. 6 (Harrich Dep) 38:9-39:3; Ex. 39 (McDonald Dep.) 13:20-17:25, 67:22-68:15. EndoWrists repaired by IRCs are functional substitutes for new EndoWrists according to the hospitals that have used the repaired versions. *Id.* Ex. 1 (Elhauge Report) ¶ 296; Ex. 77 (Intuitive-00552993); Ex. 34 (Scoville Dep.) 34:4-35:6, 105:1-14. Repaired EndoWrists also place competitive

constraints on new EndoWrists, making them economic substitutes as well. *Id.* Ex. 1 (Elhauge Report) ¶¶ 158-61 (noting Intuitive's acknowledgment that each repair by IRCs "effectively displaced one new instrument sale by Intuitive" and other evidence of price-constraining effects).

Although the determination of the relevant market is typically a fact-intensive inquiry, Intuitive has not proffered any facts that rebut the Hospital Plaintiffs' showing regarding the field of competition for EndoWrists. This analysis differs from the purported market for surgical robots in which Intuitive's expert raises a factual dispute regarding practical and economic substitutes for MIRS, i.e., at least laparoscopic and potentially open surgical methodologies, because Intuitive here fails to show any practical or economic substitute for EndoWrist instruments. Accordingly, the Hospital Plaintiffs are entitled to judgment on the definition of a market for EndoWrist repair and replacement.

2. Intuitive's Market Power and Monopoly Power in EndoWrist Market

"Market power is the power 'to force a purchaser to do something that [they] would not do in a competitive market.' It has been defined as 'the ability of a single seller to raise price and restrict output.'" *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 464 (1992); *see also Aya Healthcare Servs. v. AMN Healthcare, Inc.*, 9 F.4th 1102, 1112 (9th Cir. 2021) (stating that "'[m]arket power is the ability to raise prices above those that would be charged in a competitive market'"). Monopoly power is slightly different than market power – "Monopoly power under § 2 requires, of course, something greater than market power under § 1." *Eastman Kodak*, 504 U.S. at 481; *see also Image Tech. Servs. II*, 125 F.3d at 1206 (same). Courts have described monopoly power as "substantial" market power or an "extreme degree" of market power. *See, e.g.*, *Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F.2d 887, 894 (10th Cir. 1991); *Deauville Corp. v. Federated Dep't Stores, Inc.*, 756 F.2d 1183, 1192 n.6 (5th Cir. 1985); *see also Safeway Inc. v. Abbott Lab'ys*, 761 F. Supp. 2d 874, 886 n.2 (N.D. Cal. 2011) (defining monopoly power as a substantial degree of market power). To demonstrate market power through direct evidence, a plaintiff must present evidence "of the injurious exercise of market power" such as "evidence of restricted output and supracompetitive prices." *Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995). To demonstrate market power indirectly, a plaintiff must: "(1) define the relevant

market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry and show that existing competitors lack the capacity to increase their output in the short run." *Id.* at 1434.

The Hospital Plaintiffs do not attempt to demonstrate Inutitive's market power in the EndoWrist repair and replacement market through direct evidence, focusing instead on indirect evidence. Having defined that relevant market, the Court turns to assess whether the remaining two elements support a finding that Intuitive has monopoly power in the EndoWrist market.

To establish a prima facie case of monopoly power, courts generally require a market share of at least 65%. *Image Tech. Servs. v. Eastman Kodak*, 125 F.3d at 1206; *see also Hunt-Wesson Foods, Inc. v. Ragu Foods, Inc.*, 627 F.2d 919, 924-25 (9th Cir. 1980) ("market shares on the order of 60 percent to 70 percent have supported findings of monopoly power"). "By contrast, Section 1 claims can be satisfied with less market power." *Epic Games, Inc. v. Apple Inc.*, 559 F. Supp. 3d 898, 1029 (N.D. Cal. 2021), aff'd in part, rev'd in part and remanded, 67 F.4th 946 (9th Cir. 2023) (citation omitted). Courts considering monopoly power under Section 2 have also required that such "power be beyond fleeting or ephemeral," which courts have interpreted to mean "durable and sustaining." *Epic Games*, 559 F. Supp. 3d at 1028 (citing *United States v. Syufy Enters.*, 903 F.2d 659, 665-66 (9th Cir. 1990)). "In evaluating monopoly power, it is not market share that counts, but the ability to *maintain* market share." *Syufy Enters.*, 903 F.2d at 665-66 (emphasis in original).

Entry barriers are market characteristics "that prevent new rivals from timely responding to an increase in price above the competitive level." *FTC v. Qualcomm Inc.*, 411 F. Supp. 3d 658, 684 (N.D. Cal. 2019) (quotation marks omitted), rev'd on other grounds, 969 F.3d 974 (9th Cir. 2020). Such barriers to market entry generally include "additional long-run costs that were not incurred by incumbent firms but must be incurred by new entrants," or "factors in the market that deter entry while permitting incumbent firms to earn monopoly returns." *L.A. Land Co. v. Brunswick Corp.*, 6 F.3d 1422, 1427-28 (9th Cir. 1993) (quotation marks omitted). Barriers to entry may include, for example, "(1) legal license requirements, (2) control of an essential or superior resource, (3) entrenched buyer preferences for established brands; (4) capital market

evaluations imposing higher capital costs on new entrants; and, in some situations, (5) economies of scale." *Rebel Oil Co.*, 51 F.3d at 1439 (citing *L.A. Land Co.*, 6 F.3d at 1428 n.4).

Here, Intuitive's market share in the EndoWrist repair and replacement market has been at least 99.87% since 2017, with IRC-repaired EndoWrists making up the miniscule remainder. *See* Corrigan Decl. Ex. 1 (Elhauge Report) ¶ 179 n.436 & Table 2 (calculating market share).[7] Such a high rate of market share exceeds the 65% figure typically considered sufficient to establish monopoly power, and it far exceeds the share deemed sufficient to establish market power. Intuitive presents no conflicting evidence or argument that it maintains a lesser share of the EndoWrist repair and replacement market.

Intuitive's monopoly power is protected by high entry barriers. Corrigan Decl. Ex. 1 (Elhauge Report) ¶¶ 180-85. Intuitive's prohibitions on third-party EndoWrist repair effectively lock out competitors. *Id.* Ex. 79 (Parker Dep.) 130:6-23, 139:23-140:8. Technological barriers also present a significant hurdle, including because to repair EndoWrists for use beyond their preprogrammed use-counter limits, IRCs must be able to reset the counter chip. IRCs have made significant investments to perform such resets. *Id.* Ex. 80 (REBOTIX110980) at -981; Ex. 1 (Elhauge Report) ¶¶ 262, 275; Ex. 26 (Hamilton Dep.) 42:1-11; Ex. 54 (Intuitive 10K FY2020) at 12.

Significantly, Intuitive's power in the EndoWrist repair and replacement market also has staying power – Intuitive has ensured that it will maintain its market share by prohibiting EndoWrist repair and mandating that customers purchase new replacement EndoWrists only from Intuitive. *See* Corrigan Decl. Ex. 1 (Elhauge Report) ¶ 242; Ex. 36 (Madewell Dep.) 119:8-18. Intuitive maintains customer returns by threatening to discontinue their robot service, warranty, and future supply of instruments if the customers are found to use IRC-repaired EndoWrists. *Id.* Ex. 1 (Elhauge Report) ¶ 242; *see also* Intuitive's Answer (ECF 74) ¶¶ 82, 107. The prohibition on using IRC-repaired instruments is a standard contract provision, binding every Intuitive customer throughout the United States since at least 2017. Corrigan Decl. Ex. 38 (Bair Dep.)

[7] Prof. Elhauge's calculations correspond with the "Class Period" in this putative class action, which reaches from May 21, 2017, to present. Amended Complaint ¶ 163.

99:24-100:8; Ex. 17 (Smith Report) ¶ 84(a). Intuitive's overwhelming share of the market for EndoWrist repair and replacement thus weighs heavily towards findings of both monopoly and market power. In the absence of countervailing evidence or a meaningful counterargument from Intuitive, the Court concludes that the Hospital Plaintiffs are entitled to judgment on the issues of monopoly power and market power in the market for EndoWrist repair and replacement.

II. INTUITIVE'S CROSS-MOTION

In addition to opposing the Hospital Plaintiffs' motion, Intuitive moves for summary judgment on the entirety of the Hospital Plaintiffs' antitrust claims. Antitrust plaintiffs must not only prove the existence of a contract that is intended to and actually does restrain trade, but also show antitrust standing, which includes antitrust injury. *See Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1197 (9th Cir. 2012); *see also Am. Ad Mgmt., Inc. v. Gen. Tel. Co. of California*, 190 F.3d 1051, 1054-55 (9th Cir. 1999).

Having defined the relevant market and found both market and monopoly power with regard to EndoWrist repair and replacement, the Court turns to the additional portions of the antitrust assessment on which Intuitive seeks summary adjudication, including (a) whether Hospital Plaintiffs have established antitrust standing and (b) whether the rule of reason analysis can be resolved in Intuitive's favor at this stage.

A. Antitrust Standing

Intuitive's cross-motion for summary judgment attacks the Hospital Plaintiffs' proof of antitrust standing related to EndoWrists, as well as with regard to da Vinci servicing. After setting forth the legal standard for antitrust standing, the Court considers Intuitive's arguments about EndoWrists and then those related to da Vinci servicing.

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1. Legal Standard

There is no exact standard by which to measure antitrust standing, but the Ninth Circuit requires trial courts to balance the following factors in making its assessment:

> (1) the nature of the plaintiff's alleged injury; that is, whether it was the type the antitrust laws were intended to forestall;
> (2) the directness of the injury;
> (3) the speculative measure of the harm;
> (4) the risk of duplicative recovery; and
> (5) the complexity in apportioning damages.

Am. Ad Mgmt., Inc. v. Gen. Tel. Co. of Cal., 190 F.3d 1051, 1054 (9th Cir. 1999) (citations omitted). "[N]o single factor is decisive," but courts give "great weight to the nature of the plaintiff's alleged injury." *Id.* at 1054 (citations omitted).

There are four requirements for showing antitrust injury: "(1) unlawful conduct, (2) causing an injury to the plaintiff, (3) that flows from that which makes the conduct unlawful, and (4) that is of the type the antitrust laws were intended to prevent." *City of Oakland v. Oakland Raiders*, 20 F.4th 441, 456 (9th Cir. 2021) (quoting *Am. Ad Mgmt.*, 190 F.3d 1051, 1055 (9th Cir. 1999) (quotations omitted); *see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977). In particular, antitrust injury "ensures that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342 (1990).

2. Antitrust Standing – EndoWrists

Intuitive brings three challenges to the causal link between the alleged antitrust violations and the damages sought by the Hospital Plaintiffs, including that (1) FDA's regulatory scheme, not Intuitive's conduct, prevented IRCs from entering the EndoWrist repair market; (2) Plaintiffs cannot attribute the absence of competitors in the EndoWrist repair market to Intuitive because they expressed no interest in utilizing such services, and (3) Plaintiffs cannot prove causation of injury arising from the X/Xi EndoWrist instruments because no entity has yet repaired the X/Xi models. The Court considers each argument.

a. FDA Regulations and Antitrust Injury[8]

Intuitive argues that the Hospital Plaintiffs cannot establish antitrust injury as to aftermarket EndoWrist services because nearly all the entities offering such services violated the Food, Drug and Cosmetic Act ("FDCA") by failing to obtain Section 510(k) clearance. In other words, none of the Hospital Plaintiffs' claimed injuries are directly attributable to Intuitive's allegedly anticompetitive conduct because the regulatory bar of Section 510(k) clearance breaks the chain of causation. Intuitive's argument relies on the legal conclusion that the IRCs violated the FDCA.

Intuitive cites several cases for the premise that the Hospital Plaintiffs lack antitrust standing based on the alleged unlawfulness of the third-party repair companies' conduct. Intuitive Opp. & Cross-Mot. at 13-14 (citing *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 163- 65 (3d Cir. 2017); *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791-92 (8th Cir. 2006); *Modesto Irrigation Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156, 1170 (N.D. Cal. 2004) aff'd, 158 F. App'x 807, 807 (9th Cir. 2005)). The cases cited by Intuitive, in which a regulatory impediment to a competitor's business was considered in the context of antitrust standing, involved regulatory schemes that unquestionably would have made the competitor's business unlawful. In the *Wellbutrin* case, for example, plaintiffs claimed that they suffered injury in the form of increased drug prices, and that those increased prices were caused by defendants' conspiracy to delay the launch of a generic form of the drug. *Wellbutrin*, 868 F.3d at 164-65. The court found that the generic form of the drug could not have been legally produced because a patent blocked its release, and because plaintiffs could not prove that the defendant's actions "actually cause[d] the [plaintiffs'] claimed injury," their claim failed. *Id.* at 166.

Similarly, in *Modesto Irrigation District*, the plaintiff complained that Pacific Gas & Electric interfered with its attempt to offer competing electric service in Pittsburg, California. *Id.*, 309 F. Supp. 2d at 1159-60. The district court held that the plaintiff could not prove antitrust injury because it "possessed neither the legal right, nor the necessary [regulatory agency]

[8] The Court's analysis and conclusion in this section are substantially similar to the analysis and discussion in the Court's order in the related case, *Surgical Instrument Service Co. v. Intuitive Surgical, Inc.*, N.D. Cal. Case No. 21-cv-3496, also entered today.

permission to expand its service into Pittsburg." *Id.* at 1170. The court found that because the plaintiff's "conduct was unlawful by its own terms, PG&E's response – however anti-competitive or seemingly monopolistic – could not inflict an cognizable antitrust injury." *Id.*

Here, in contrast to those cases, Intuitive cannot establish, nor can the Court find, that the IRCs violated the FDCA because FDA has not concluded that Section 510(k) clearance is required for the aftermarket EndoWrist service.

The FDCA bars private enforcement of the statute, providing that all FDCA enforcement actions, including those to restrain violations, "shall be by and in the name of the United States." 21 U.S.C. § 337(a). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4. The Ninth Circuit determined after *Buckman* that "[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when . . . the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). In *PhotoMedex*, the Ninth Circuit considered a dispute as to whether a new version of dermatological laser required pre-market Section 510(k) clearance separate from that obtained for an earlier version. *Id.* at 926. The court affirmed a grant of summary judgment in favor of the defendant on a Lanham Act false advertising claim based on allegations that the defendant misrepresented that its product had received FDA clearance. *Id.* at 922. The court noted that the FDA had not taken a position on the laser's need for Section 510(k) clearance and held that "[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *Id.* at 924.

To be sure, the FDCA does not preclude all Lanham Act claims. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 120 (2014) (permitting a Lanham Act claim challenging FDA regulated food label as misleading). However, courts have consistently precluded private actions

which require establishing a violation of the FDCA.[9] *See, e.g., Amarin Pharma, Inc. v. International Trade Commission*, 923 F.3d 959, 968 (Fed. Cir. 2019) (citing *PhotoMedex*, 601 F.3d at 924, 928) (finding that Lanham Act claim could not stand where it was "based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA.").

Intuitive asks the Court to find that the Hospital Plaintiffs did not suffer an injury of the type the antitrust laws were intended to prevent because the IRCs engaged in "remanufacturing" by resetting the EndoWrist use counters and violated 21 C.F.R. § 807.81 by offering such services to consumers without first obtaining Section 510(k) clearance. However, the FDA has expressly disclaimed concluding that a violation exists, and it has taken no final position on the need for 510(k) clearance here. *See, e.g.*, Cahoy Decl. Ex. 37 (email from FDA Team Lead clarifying that his message was not an "official regulatory evaluation" and did "not represent the formal position of FDA"). Despite Intuitive's repeated entreaties for the Court to find that informal communications made FDA's position clear, that is not so.[10] Additionally, and as others before it, the Court declines Intuitive's invitation to step into the FDA's shoes and determine whether the IRCs' services require Section 510(k) clearance. *See Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, No. 8:20-CV-2274-VMC-TGW, 2022 WL 3272538, at *5 (M.D. Fla. Aug. 10, 2022); *Restore Robotics, LLC v. Intuitive Surgical, Inc.*, No. 5:19-cv-55-TKW-MJF, 2019 WL 8063988, at *2-3 (N.D. Fla. Nov. 14, 2019) (finding this determination more properly within the exclusive

[9] In his order denying Intuitive's motion to dismiss earlier in the case related to this one, Judge Chhabria concluded that *PhotoMedex* had been "effectively overruled" by the Supreme Court in *POM Wonderful*. *Surgical Instrument Serv. Co., Inc. v. Intuitive Surgical, Inc.*, 571 F. Supp. 3d 1133, 1142 (N.D. Cal. 2021). This Court takes a different approach – it does not appear that *PhotoMedex* has been effectively overruled because the Ninth Circuit expressly relied on its reasoning in restating the court's continued fidelity to the principle that the FDA maintains exclusive enforcement authority over the FDCA. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1048 (9th Cir. 2022). The opinion of the panel in *Nexus Pharmaceuticals*, issued after Judge Chhabria's order denying dismissal, included *PhotoMedex* in a survey of cases that found state law tort claims preempted by the FDA's enforcement authority. *Id.* at 1048.

[10] This Court is in good company concluding that these informal communications do not constitute a final FDA action. *See Restore Robotics*, 2019 WL 8063988, at *2-3; *Rebotix Repair*, 2022 WL 3272538, at *5.

purview of FDA). Because FDA has not determined whether 510(k) clearance is necessary for IRCs' aftermarket EndoWrist services, there is no regulatory bar to the Hospital Plaintiffs' antitrust injury. The Court does not conclude that the IRCs were not required to obtain pre-market Section 510(k) clearance; rather, it concludes only that Intuitive, a private litigant, may not litigate the alleged FDCA violation through a standing challenge where the FDA has not itself found such a violation. Intuitive's motion is DENIED on this basis.

b. Plaintiffs' Interests in Remanufactured EndoWrists

Intuitive argues that the Hospital Plaintiffs did not suffer antitrust injury by the lack of access to EndoWrist repair services because none of the Plaintiffs would have utilized such repaired instruments. To this end, Intuitive cites to several out-of-circuit cases in which courts found that plaintiffs lacking contemporaneous interest in a competitor's offering lacked standing to pursue antitrust claims at least in part because they were not active market participants. *See* Intuitive Opp. & Cross-Mot. at 19 (citing *St. Louis Convention & Visitors Comm'n v. Nat'l Football League*, 154 F.3d 851, 862-64 (8th Cir 1998); *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 716-17 (E.D. Pa. 2020); *Elison v. Amer. Bd. of Orthopaedic Surgery*, 11 F.4th 200, 208-10 (3d Cir. 2021); *Amer. Express Anti-Steering Rules Antitrust Litig.*, 19 F.4th 127, 140-41 (2d Cir. 2021)).

Intuitive contends that numerous witnesses for the Hospital Plaintiffs confirmed that if FDA took the position that remanufactured EndoWrists required FDA clearance they would not use them. *See* Cahoy Decl. Ex. 67 (Schimmel Dep.) at 51:24-52:8, Ex. 68 (Teal Dep.) at 37:11-25, 43:2-8, Ex. 69 (Early Dep.) at 58:13-18. Intuitive assumes that FDA requires EndoWrist repair services to receive Section 510(k) clearance and accordingly infers that the Hospital Plaintiffs have no interest in using the repaired instruments. *See, e.g.*, Spector Decl. Ex. 132 at 37:18-19 ("[I]f the FDA requires a device to be cleared, . . . [Valley] would purchase a cleared device."). But for the reasons discussed above, Intuitive's assumption is wrong – FDA has taken no enforcement action to require Section 510(k) clearance for EndoWrist repair – and Intuitive's hypothetical is therefore inapplicable.

Further, the Hospital Plaintiffs have testified they are interested in utilizing repaired EndoWrists, but they have not sought to utilize such services because of contractual barriers imposed by Intuitive. *See* Spector Decl. Ex. 126 (Waninger Dep.) at 36:13-37:2 (Franciscan); Spector Decl. Ex. 134 (Gonzalez Dep.) at 14:10-15:4, 25:6-26:15, 81:9-84:14 (Larkin). Franciscan and Larkin additionally proffer evidence that they did not engage with the IRCs due to concerns that Intuitive would cancel their da Vinci warranties, one of the allegedly anticompetitive allegations at the heart of this case. *See* Spector Decl. Ex. 126 at 36:23-37:2 (Franciscan); Ex. 135 (Wagner Dep.) at 25:6-26:15 (Larkin). The Hospital Plaintiffs' interest in repaired instruments sets this case apart from the authorities cited by Intuitive for the premise that plaintiffs lack antitrust standing based on disinterest in competitors' goods. *See, e.g.*, *Niaspan*, 464 F. Supp. 3d at 716-17 (finding lack of standing for consumers uninterested in purchasing generic rather than name-brand pharmaceutical).

Plaintiffs additionally offer competing evidence of a market-wide impact theory. Plaintiffs' economic expert indicates that, absent Intuitive's exclusionary restraints, Intuitive would have lowered EndoWrist prices and/or increased their artificially suppressed use limits for all customers to meet IRC competition. *See* Corrigan Decl. Ex. 1 (Elhauge Report) § VI.A-C. Importantly, Plaintiffs contend, they all purchased EndoWrist instruments and thus participated in the relevant market. *See In re Optical Disk Drive Antitrust Litig.*, No. 3:10-MD-2143 RS, 2016 WL 467444, at *5 (N.D. Cal. Feb. 8, 2016) (relying on expert testimony regarding market-wide impact in antitrust injury assessment).

Considering all this evidence, some of it conflicting with Intuitive's contention that the Hospital Plaintiffs were uninterested in repaired devices, Plaintiffs have put forth enough to show antitrust standing. *See, e.g.*, Spector Decl. Ex. 126 at 36:13-17 (discussion of interest in IRC services at Franciscan); Ex. 134 at 14:10-15:4 (same at Larkin). There is evidence from which a jury could conclude that Intuitive's allegedly anticompetitive conduct was a material cause of the Hospital Plaintiffs' injuries. Intuitive's motion is DENIED on this basis.

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c. IRC Repair of X/Xi EndoWrists

Despite Intuitive's hypothetical-premised argument above, it argues that Plaintiffs cannot rely on hypotheticals regarding IRC repair of certain EndoWrists. Plaintiffs cannot establish antitrust injury as to the X/Xi EndoWrists, Intuitive contends, because "there has never been an entity in the marketplace with the *ability* to modify X/Xi EndoWrists to reset their use counters." Intuitive's Cross-Motion at 26.

Countering Intuitive's arguments regarding the inability for IRCs to repair the X/Xi instruments, the Hospital Plaintiffs cite to testimony that IRCs know how to conduct such repair, but they have not done so in light of what they view as Intuitive's market interference. *See* Spector Decl. Ex. 119 (Hamilton Dep.) at 39:14-40:22, 41:17-25; Corrigan Decl. Ex. 1 (Elhauge Report) ¶¶ 163, 263-64, 275; *id.* Ex. 2 ¶ 416. Intuitive emphasizes that such testimony amounts to mere speculation. Intuitive Reply Br. at 14. The testimony advanced by the Hospital Plaintiffs from the entities prepared to compete and repair the X/Xi instruments, however, constitutes more than mere conjecture, and it instead creates a genuine dispute of fact regarding the injury to the Hospital Plaintiffs and the market more broadly. *Cf. Rebotix*, 2022 WL 3272538, at *9 (rejecting Intuitive's argument that Rebotix lacked antitrust standing based on the X/Xi EndoWrists due to similar dispute of fact even where Rebotix had not yet achieved X/Xi use counter interception). Intuitive invites the Court to only consider what competitors have accomplished rather than what they report they can or would achieve absent anticompetitive conduct, but Intuitive cites no authority to that end. Indeed, "[t]o establish impact in any antitrust action," plaintiffs are often required to compare "the actual world with a 'hypothetical' world that would have existed 'but for' the defendant's unlawful activities." *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 993 F.3d 774, 788 (9th Cir.), reh'g en banc granted, 5 F.4th 950 (9th Cir. 2021), and on reh'g en banc, 31 F.4th 651 (9th Cir. 2022), cert. denied sub nom. *StarKist Co. v. Olean Wholesale Grocery Coop., Inc., On Behalf of Itself & All Others Similarly Situated*, 143 S. Ct. 424 (2022) (quotation marks omitted). Thus, the Court considers the testimony offered by Plaintiffs to compare the actual world with the hypothetical world of EndoWrist repair but for Intuitive's conduct. Given that evidence, the Court cannot, as a matter of law, conclude that Plaintiffs

suffered no antitrust injury related to the X/Xi instruments. Intuitive's motion is DENIED on this basis.

3. Antitrust Standing – Da Vinci Servicing

Intuitive additionally argues that the Hospital Plaintiffs cannot establish that Intuitive caused antitrust injury related to servicing for da Vinci Systems. Foundational to its argument is the fact that IRCs are incapable of providing the full gambit of da Vinci maintenance because some portion of the servicing requires use of Intuitive's proprietary technology. Plaintiffs have conceded that Intuitive held no duty to share or disclose this proprietary technology with third parties. ECF 69 (Order denying motion to dismiss) at 2. In light of the incomplete service offering, Intuitive posits, "it would have made no economic sense for most customers . . . to employ [IRCs]." Intuitive Opp. & Cross-Mot. at 20. Intuitive argues further that, because the majority of da Vinci owners have comprehensive service contracts with Intuitive, such third-party servicing would constitute an additional and redundant expense. *See* Bair Decl. ¶¶ 5, 9.

The Hospital Plaintiffs present competing evidence that at least one IRC, Restore, in fact provided some da Vinci maintenance services. Corrigan Decl. Ex. 50 (sales report from Restore). Further, there existed at least some supply of IRCs willing and capable of providing the service even without Intuitive's proprietary technology, *see id.*, and there existed demand for IRC da Vinci service, *see* Spector Decl. Ex. 148 (email re: Power Supply Replacement, January 12, 2020); *see also* Ex. 137 (Parker Dep.) at 162:16-25. But Intuitive impeded da Vinci owners from obtaining IRC service by refusing to permit in-house repair (*id.* Ex. 126 (Waninger Dep.) at 21:8-21, 60:12-15) and by issuing threats that owners risked "the cancelling of any warranties or cancelling of the service contract" if "somebody else does perform service" (Ex. 143 (Thomas Dep.) at 37:22-38:7). The Hospital Plaintiffs present evidence that, but for Intuitive's interference and servicing prohibitions, IRCs could have provided some level of service at discounted prices, which would have resulted in Intuitive competing on price. Corrigan Decl. Ex. 1 (Elhauge Report) ¶¶ 234, 365-66, 412-14. Their expert, Prof. Elhuage, offers a reliable damages calculation showing significant overcharges for each named Plaintiff and the purported class. *Id.*, Table 8. The Hospital Plaintiffs' payment of these supracompetitive prices for da Vinci servicing as a result

of Intuitive's allegedly anticompetitive conduct is plainly an injury "of the type the antitrust laws were intended to prevent." *Brunswick*, 429 U.S. at 489. The Hospital Plaintiffs thus present sufficient evidence to preclude summary adjudication on this issue in favor of Intuitive. *See also Restore*, 2022 WL 1495005, at *4 (considering similar evidence, holding that a "jury could find that as a matter of 'market reality,' Intuitive effectively forces customers into using its da Vinci repair services (even those services that do not require the distributor's toolkit)" and "that Restore could (and did) still perform some services on the da Vinci without access to that technology but for the impacts of the exclusive dealing provisions of" Intuitive's agreements).

B. Rule of Reason

In addition to seeking judgment as a matter of law on antitrust injury, Intuitive asks the Court to grant it judgment on the merits of the Hospital Plaintiffs' antitrust claims. Because the Hospital Plaintiffs' claims are not premised on a per se violation of the antitrust laws, the rule of reason applies to each of their theories of antitrust liability. *See Flaa v. Hollywood Foreign Press Ass'n*, 55 F.4th 680, 688 (9th Cir. 2022).

The rule of reason calls on courts to conduct a fact-specific assessment of market power and structure to assess a restraint's actual effect on competition. *Fed. Trade Comm'n v. Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020). Under the rule of reason's framework:

> the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.

Ohio v. Am. Express Co., 585 U.S. 529, 541 (2018) (citing 1 Kalinowski § 12.02[1]; P. Areeda & H. Hovenkamp, Fundamentals of Antitrust Law § 15.02[B] (4th ed. 2017); *Capital Imaging Assoc., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2nd Cir. 1993)).

Intuitive only challenges the Hospital Plaintiffs on the second and third steps. The Court considers the arguments presented in the parties' briefing regarding the second step of the rule of reason analysis and, in so doing, assumes without deciding that the Hospital Plaintiffs can carry

their initial burden of showing the anticompetitive effects of Intuitive's conduct for purposes of this discussion.

A procompetitive rationale is a "nonpretextual claim that [defendant's] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." *Qualcomm*, 969 F.3d at 991. It is not enough that "conduct 'has the effect of reducing consumers' choices or increasing prices to consumers.'" *Id.* at 990 (quoting *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012)). For example, the Ninth Circuit affirmed a finding that Apple "offered non-pretextual, legally cognizable procompetitive rationales for its" anticompetitive conduct, including restrictions it imposed to promote user privacy and security. *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 985, 987-89 (9th Cir. 2023), cert. denied, 144 S. Ct. 681 (2024), and cert. denied, 144 S. Ct. 682 (2024).

Intuitive argues that the antitrust laws do not penalize a defendant that had a "reasonable basis to conclude that its [challenged] actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority." *Phonetele, Inc. v Amer. Tel. & Tel. Co.*, 664 F.2d 716, 737-38 (9th Cir. 1981); *see also In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 12 (1st Cir. 2020) (concluding that regulatory justification defense can defeat antitrust claim if defendant's decision was reasonable and made in good faith). Based on this authority, Intuitive contends that it had a reasonable basis for concluding that EndoWrist use limits were necessary, a conclusion it says FDA affirmed by its initial approval of the instruments. The same reasoning underlies Intuitive's efforts to ensure that the use limits were not circumvented, it contends, including letters sent to customers and the FDA. Intuitive avers that it had a reasonable basis to act, satisfying the second step.

Intuitive's argument regarding its "reasonable bases" for anticompetitive conduct misstates what the rule of reason requires and thus short-circuits. To the extent Intuitive argues that its anticompetitive behavior arose from a good-faith attempt to ensure patient safety and compliance with FDA regulations, it has failed to provide a nonpretextual "procompetitive rationale." *See Qualcomm*, 969 F.3d at 991. Moreover, the Hospital Plaintiffs challenge Intuitive's position as pretextual and present conflicting evidence that, for example, the EndoWrist use counter does not

impact patient safety outcomes. *See* Corrigan Decl. Ex. 7 (Rubach Report) ¶¶ 12, 28-36; Ex. 1 (Elhauge Report) ¶ 835; Ex. 3 (Elhauge Reply) ¶¶ 384-98. Similarly, the Hospital Plaintiffs present evidence that Intuitive's effort to ensure regulatory compliance amounts to mere pretext. Corrigan Decl. Ex. 33 (internal correspondence from Intuitive's Senior Director of Regulatory Affairs stating, "Just so you know, FDA does not require nor limit the number of uses for our [EndoWrist] instruments.") Given this countervailing evidence, which the Court must view in the light most favorable to the Hospital Plaintiffs as the non-moving party on this issue, Intuitive is not entitled to summary adjudication on the issue of its procompetitive rationale.

Because Intuitive fails to identify any nonpretextual procompetitive justifications, the Court does not reach the issue of whether the Hospital Plaintiffs can demonstrate the existence of less restrictive alternatives. Intuitive is not entitled to summary judgment on the Hospital Plaintiffs' antitrust claims.

CONCLUSION

For the foregoing reasons, the Court **GRANTS in part and DENIES in part** the Hospital Plaintiffs' Motion for Summary Adjudication, and the Court **DENIES** Intuitive's cross-motion.

The Court **DENIES** Intuitive's motion for leave to file supplemental authority. The Court **DENIES** the Hospital Plaintiffs' motion for leave to file supplemental authority. The Court **DENIES** the Hospital Plaintiffs' motion for leave to file a sur-reply.

The Court resolves Intuitive's several motions to exclude expert testimony as well as the parties' several administrative motions to seal in separate orders.

This Order is filed under seal. The parties shall meet and confer with each other and any appropriate non-parties, and on or before April 26, 2024, submit a new proposed redacted version of this Order that incorporates the Court's rulings on the administrative motions to seal.

IT IS SO ORDERED.

Dated: March 31, 2024

ARACELI MARTÍNEZ-OLGUÍN
United States District Judge